Application No.: 10/772124 Docket No.: CL2175USNA Reply to Office Action of 1 Jun 05

### **REMARKS**

Claims 1-22 are pending in the application, which were rejected in the Office Action under 35 USC 102(b) and 35 USC 103(a).

Claims 1, 7, and 8 have been amended to more clearly define Applicants invention. Claims 3-4 have been canceled.

## Specification

The specification is objected because of discrepancies between the sequence illustrated in formula 1 (page 14) as compared with claim 7 and formula 2 as compared with SEQ ID NO:4 to which it is attributed.

Applicants find no discrepancy between the sequence illustrated in formula 1 (page 14) as compared with claim 7. In a telephone conversation with the Examiner Applicants' representative asked the Examiner for clarification of this objection. The Examiner suggested that Applicants note in this paper that the objection was not clarified and further suggested that Applicants invite the Examiner to re-assert the objection in a later paper. Applicants' representative thanks the Examiner for his help and suggestion and invites him to revisit the objection when clarified.

The discrepancy between formula 2 as compared with SEQ ID NO:4 has been clarified by amendment. Formula 2 is now correctly attributed to SEQ ID NO:9.

#### Sequence Listing

Applicants file a substitute Sequence Listing herewith, adding sequence listings numbered 5-14. The amendment of the sequence listing herein does not introduce new matter as sequences numbered 5-14 were included in the specification as of the date the application was filed. Additionally, this response amends the specification to accordingly correct the Brief Description of Sequence Listings and to insert references to the added sequence listings on pages 14-15.

Accompanying this response is:

- 1) A substitute paper copy of the Sequence Listings;
- 2) a replacement computer readable form of the Sequence Listing; and a Declaration Under 37 CFR 1.821(f) and 1.825(a) asserting the identity of the substitute copy of the computer readable form with the amended Sequence Listing and that the added sequence listings are supported in the specification as filed.

# Claim Rejections - 35 USC § 102

Under 35 USC 102(b), the Office Action rejected all claims as being anticipated by US Pat. No. 6,280,747 to Philippe et al. ["Philippe"]. It is the Examiner's opinion that Philippe

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teach the claimed cosmetic ingredients in combination with the claimed protein. Applicants traverse.

For a rejection to be valid under 35 USC § 102 each and every element of the claimed invention must be contained in the cited reference. Claim 1 has been amended to add the elements of claim 4 and is independently supported in the specification at least at page 16, lines 34-37.

The claims as amended teach skin and hair care or hair coloring compositions comprising water-soluble silk protein, wherein the silk protein is expressed in microbial expression systems, is purified by precipitation at a temperature below about 20 °C and redissolves in water. Philippe does not recite all of the claimed elements expressly or inherently and therefore does not teach the recited composition. In particular, Philippe does not teach the purification by precipitation at a certain temperature and the re-dissolution of the precipitated silk protein.

#### Claim Rejections - 35 USC § 103

All claims stand rejected under 35 USC 103(a) as being unpatentable over Philipe in view of US Pat. No. 5,760,004 to Stedronsky ("Stedronsky").

In making this rejection the Examiner presumes that the subject matter of the various claims was commonly owned at the time the invention was made. The Examiner's presumption is correct.

The teaching of Philipe is given above. Stedronsky is cited for the teaching methods by which the solubility of water soluble polymers, and particularly proteins, may be enhanced through chemical modification.

The examiner reasons that it would have been obvious to the skilled person to make the shorter polymers of the monomers taught by Philippe so as to make the polymers more water soluble as taught by Stedronsky. Applicants traverse.

It is axiomatic that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The combined teachings of Philippe and Stedronsky fail all three criteria.

Applicants are unclear as to the examiner's rationale for this rejection under 35 USC § 103. The examiner states that it would have been obvious to make shorter polymers (Philippe) so as to make them water soluble as taught by Stedronsky. However Stedronsky teaches that chemical modification with functionalizing agents makes polymers water soluble and not

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shortening the polymers (Column 2, line 60 through Column 3). Applicants request clarification.

The present disclosure does not suggest using short polymers nor chemical modification to attain water solubility. Rather water solubility is achieved and maintained via the low temperature purification process according to the limitations of original Claim 4, and now amended Claim 1. The preferred water-soluble silk proteins of the instant invention have a preferred molecular weight of from about 40,000 to about 500,000 daltons (see page 13, lines 14-17), far in excess of the polymers of Philippe. Because the present disclosure does not suggest chemical modification to achieve water solubility, Applicants submit that there is no motivation to combine the cited references to achieve the invention.

Similarly, a combination of the cited references would not give the skilled person a reasonable expectation of success as the elements of the invention are not taught in the cited references.

Finally, the combination of the cited references do not teach or suggest all the claim limitations. In particular, short polymers are not taught, and low temperature purification is not taught.

In view of the foregoing, Applicants request withdrawal of all rejections and reconsideration of the claims as amended.

Respectfully submitted,

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